

EXHIBIT 13

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

HO *et al.*

Appl. No.: 09/960,244

Filed: September 21, 2001

For: **Cell Populations Which Co-Express
CD49c and CD90**

Confirmation No.: 4326

Art Unit: 1651

Examiner: Leon B. Lankford, Jr.

Atty. Docket: 2560.0020000/JAG/D-S

Petition Under 37 C.F.R. § 1.181

Mail Stop Petitions
U.S. Patent & Trademark Office
PO Box 1450
Alexandria, Virginia 22313-1450

Sirs:

Pursuant to M.P.E.P. § 608.04(c), Petitioners respectfully petition under 37 C.F.R. § 1.181(a)(1) for the Director to review and rescind the Examiner's requirement to cancel allegedly new matter submitted in Petitioners' request for amendment of March 5, 2008 in the above-referenced patent application.

Statement of the facts, points to be reviewed, and action requested pursuant to 37 C.F.R. § 1.181

On March 5, 2008, in response to a non-final Office Action,¹ Petitioners submitted an Amendment and Reply ("Reply") in the above-referenced patent application (copy of Reply attached herewith as **Exhibit A**). During the preparation of this Reply, Petitioners discovered minor clerical errors in the specification as originally filed, and therefore sought to amend the specification (as part of the Reply) in order to provide the clearest possible disclosure and description of the invention. Petitioners note that these amendments are not material to patentability of the invention nor do they alter or effect the scope of claims previously or presently pending.

¹ Non-Final Office Action mailed October 5, 2007.

One month later, on April 3, 2008, Petitioners' Counsel held an in-person interview with the Examiner to discuss the previously issued Office Action and Petitioners response thereto. During this interview the Examiner did not comment on, nor object to, the Petitioners' request for amendments submitted in the March 5th Reply. On June 11, 2008 the Examiner requested (via email) that Petitioners submit a formal Supplemental Amendment and Reply including submission of a new claim which the Examiner recommended for consideration during the April 3rd interview. On July 7, 2008, Petitioners' submitted the requested Supplemental Amendment and Reply ("Supplemental Reply"). (Copy attached as **Exhibit B**). This Supplemental Reply did not include any request for amendments in the specification.

On March 16, 2009, the Examiner mailed a final Office Action rejecting all pending claims and objecting to one of the amendments requested in Petitioners' March 5, 2008 Reply.² (Copy of final Office Action attached as **Exhibit C**). In particular, the Examiner objected to entry of the requested amendment by alleging that the amendment introduces new matter and is, therefore, "objected to under 35 U.S.C. 132(a)." *See, Exhibit C*, page 6, second paragraph. In this regard, the Examiner stated:

The added material which is not supported by the original disclosure is as follows: applicant has amended the specification to move the description of the cells produced from Example 1 to Example 3 and this would appear to be new matter and not simply a correction of a clerical error. Methods 1 & 3 are distinct methods and it would appear by making the instant amendment, applicant is changing the description of the invention.

Id.

Petitioners respectfully submit that the Examiner is in error in objecting to the above-referenced request for this amendment because the amendment is supported by the original disclosure, the amendment does not change the description of the invention, and the amendment does not introduce new matter. *See, Ex Parte Marsili*, 214 U.S.P.Q. 904, 906 (Bd. Pat. App. & Inter. 1979) (amendment correcting structural formula to the formula inherently present in the described and exemplified compound does not constitute new matter; amendment to make correction is in the public interest).

² In fact, in the Final Office Action the Examiner incorrectly attributed the Petitioners' request for amendment to the "amendment filed 7/7/08" instead of to Petitioners' Reply of March 5, 2008 (where it was actually submitted). *See, Final Office Action (Exhibit C)*, page 6, second paragraph, first sentence.

The particular amendment objected to by the Examiner refers to Petitioners' request to move the exact same last sentence at the end of Example 1, *as originally filed*,³ to the third paragraph of Example 3. *See, Exhibit D* (copy of published patent application), pages 9 and 10, *with hand-written text in the margins to show the amendment exactly as requested*⁴. The Petitioners' request to move this sentence to the middle of Example 3 was in order to place this sentence (which refers to cells shown in Figure 1B) immediately after a sentence referring to "Master Cell Bank" cells in order to provide additional clarity that the cells shown in Figure 1B may be referred to by the arbitrary designation of "Master Cell Bank" cells. (Petitioners note that *the claims* in the present application do not refer to, nor require, any reference to "Master Cell Bank" cells as a term of the invention.) Petitioners also note that explanation and support for this amendment was provided as part of Petitioners' remarks in the Reply of March 5, 2008. *See, Exhibit A*, pages 9-11.

In view of the above, Petitioners submit that the Examiner's allegation that the requested amendment constitutes new matter is wholly in error. This amendment did not introduce new matter because *the exact same sentence*, as originally filed, is being moved from one part of the specification where it had been misplaced, to another part of the specification where it should have been placed. Moreover, this sentence is a self-contained sentence³ wherein the description of the invention does not change, and is not altered, by the change in placement of the sentence. Hence, the allegedly "added material" is, in fact, supported by the original disclosure. The Examiner is also incorrect in alleging that "Methods 1 & 3 are distinct methods and it would appear...applicant is changing the description of the invention." *See, Exhibit C*, page 6, second paragraph.

The specification does *not* teach that Examples 1 and 3 can or should be divisively parsed as "Methods 1 & 3" (this is an errant characterization by the Examiner). In fact, Example 3 describes a continuation of procedures begun in both Examples 1 and 2. This is evidenced by the first sentence of *Example 3* which reads "After 7-10 days in culture, the CFUs generated using the methods described in *Example 1* were removed from the T75 flasks..." In like manner, Example 4 also represents a continuation of the procedures described in Examples 1 through 3 (as referenced within this fourth example section). Hence, it is incorrect to characterize the procedures or methods described in each of these Examples as distinct "Methods." Furthermore, by requesting the amendment at issue the Petitioners are

³ This sentence reads "More than 94% of the adherent population was CD90 and CD49c positive (FIG. 1B)."

⁴ Exhibit D also contains hand-written text to show all amendments to the specification which were requested in Petitioners' Reply of March 5, 2008, but which were not objected to by the Examiner.

not "changing the description of the invention" because the requested amendment does not change this particular embodiment of the invention which teaches that "More than 94% of the adherent population was CD90 and CD49c positive."

Finally, Petitioners note that the Examiner did not object to an almost identical request to amend the specification by moving the last sentence of Example 2 to the last paragraph of Example 3 as allegedly introducing new matter. *See, Exhibit D*, pages 9-10. Indeed, this amendment was requested for the same purpose as the above-discussed amendment involving Example 1. Hence, this amendment, for the same reasons, also does not introduce new matter pursuant to 35 U.S.C. § 132(a).

In view of the explanations and exhibits provided herein and herewith, Petitioners respectfully ask that the Director rescind the Examiner's objection to Petitioners' request to amend the specification as submitted in Petitioners' Reply of March 5, 2008 and that the Director would direct entry of these amendments in the present application.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

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Enclosures